

SEP 26 2006

Atty Dkt. No.: 10004190-1
USSN: 09/846,058**REMARKS**

In view of the above amendments and the following remarks, the Examiner is requested to allow claims 28, 29, 31, 35, and 37-45, the only claims pending in this application.

Claims 28 and 45 have been amended to recite comparing height uniformity in, rather than of, a first direction and a second direction, and also amended to recite substrate height uniformity.

No new matter has been added.

Applicants respectfully request reconsideration of the application.

GENERAL COMMENT

The Applicants note that this is the *seventh* Office Action in this application.¹ All of the rejections set forth in this Office Action are *new*.²

The Applicants note that the claim elements which the Examiner believes render the claims inadequately described (i.e., "chemical moieties"), and inadequately enabled (i.e., "chemical moieties") were present in the claims *as originally filed*. While each of the rejections is readily addressable (see the remainder of this response), there appears to be no reason why these rejections could not have been made in the first Office Action over three years ago, or one of the five intervening Office Actions.

Likewise, The Applicants note that the claim element which the Examiner believes renders the claims indefinite (i.e., the phrase "of a first direction"), was entered into the claims in the Applicants' response to the second Office Action (dated January 13, 2004). While this rejection is also readily addressable (see the remainder of this response), there appears to be no reason why it could not have been made in the third Office Action over two years ago, or one of the three intervening Office Actions.

¹ See Office Actions dated: July 15, 2003, January 13, 2004, July 13, 2004, February 8, 2005, July 11, 2005, December 29, 2005 and July 18, 2006. There are *seven* Office Actions on the merits in this case.

² This Office Action argues that the claims are indefinite, inadequately described, inadequately enabled and anticipated. The basis of each rejection is new.

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While the Office's willingness to withdraw rejections is acknowledged and greatly appreciated, the Office is respectfully reminded that such examination methods decrease examination efficiency and increase the Applicants' prosecution costs.

Further, the MPEP states that such examination procedures should be avoided.³

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 28 and 45 were rejected under 35 U.S.C. § 112 as allegedly being indefinite. This rejection is respectfully traversed.

The Examiner queried how one can compare the height uniformity of a direction as opposed to a tangible object such as a substrate.

Present Claims 28 and 45 recite comparing height uniformity in a first direction and a second direction across a planar surface of a substrate to identify a first direction having higher substrate height uniformity than a second direction. Therefore, it should be clear that substrate height uniformity is being compared in two directions.

Withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

Claims 28, 29, 31, 35, and 37-45 were rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

The Examiner asserted that:

1. "the claims encompass the use of virtually an infinite number of substrates." Office Action at page 4. The Examiner pointed to page 21, line 20 of Applicants' specification for a disclosure that "[t]he substrates may be fabricated from any of a variety of materials." *Ibid*;

³ MPEP § 707.07(g): Piecemeal examination should be avoided as much as possible.

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2. "the methods encompass substrates that do not possess a first direction that has higher height uniformity than a second direction as required by independent claims 28, 37, 38 and 45." *Ibid*;

3. "Applicants' claims encompass substrates that likewise cannot possess a first direction that has higher height uniformity than a second direction planar to said substrate." *Ibid*;

4. "Applicants' claims encompass many substrates that cannot be 'drawn' into shapes that possesses [sic] height uniformity because these materials are either too brittle or would react with other materials at the melting temperature required for fabrication." Office Action at page 5; and

5. "no structural limitations are placed on the 'chemical moieties' that are used to form the array." *Ibid*.

The Examiner asserted further that:

as 1966). In the present case, Applicants have not set forth even a single working example of the present invention. In addition, when there is *substantial variation within the genus*, one must describe a sufficient variety of species to reflect the variation within the genus (e.g., see MPEP § 2163.05). Here, the variation within the genus would be enormous because the nature of the claimed methods would depend on the nature of the substrates employed, which are virtually limitless. Furthermore, the vast numbers of substrates do not share any common attributes that would allow a person of skill in the art to extrapolate Applicants' limited species to the vast number of currently claimed substrates. Thus, the general knowledge and level of skill in the art do not supplement the omitted description because no known structure/function relationship and/or chemical properties exists that could otherwise be used to show possession of the enormous genus. In addition, there is no known generally accepted method for producing this wide array of substrates. Thus, the claims fail to satisfy the constitutional requisite of promoting the progress of science and the useful arts since this seeks to monopolize all possible ways to achieve a given result (i.e., all substrates), far beyond those means actually discovered or contemplated by the inventor (i.e., molten glass drawn into a flat rectangular shape), so that others would have no incentive thereafter to explore a field already fully dominated.

Office Action at pages 6-7 (citations omitted).

Applicants submit that the Examiner is apparently applying an improper standard for written description. The claims contain an operability element by virtue

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of reciting a *method of fabricating an array of multiple features of different chemical moieties on a substrate surface*. Therefore, inoperative embodiments that cannot be used to practice this method are not included within the scope of the claim. *Union Carbide Chemicals & Plastics Tech. Corp v. Shell Oil Co.*, 308 F.3d 1167 (CAFC 2002). Inoperative embodiments not included in the claims need not be described, as the Examiner appears to be requiring. According to 35 U.S.C. § 112, first paragraph, the specification shall contain a written description of *the invention*. Therefore, Applicants are not required to describe (or enable) that which is not their invention.

Moreover, the Court has held that it is not a function of the claims to specifically exclude possible inoperative embodiments. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). A claim may contain operative embodiments and inoperative embodiments. There is no requirement that every embodiment be an operative embodiment. Only when the number of inoperative embodiments becomes significant, so as to require undue experimentation by the routineer to determine operative embodiments, does the issue of lack of enablement come into play. *Ibid*.

Moreover, the court has held recently that the written description requirement and enablement requirements "usually rise and fall together. That is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa." *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). Therefore, if a claim is enabled, it is described.

"Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330, 65 USPQ2d 1385 (Fed. Cir. 2003) (quoting *Enzo Biochem v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

The facts of Applicants' invention and the elements of Applicants' claims themselves provide sufficient guidance to exclude many inoperative embodiments. Those substrates that cannot possess the directional and height uniformity elements (see Examiner's assertions numbered 2-4, *supra*) of Applicants' claims are not included within those claims.

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With respect to the substrates (Examiner's assertion numbered 1, *supra*), Applicants have disclosed a list of suitable substrate materials after the sentence (in the paragraph beginning at page 21, line 20) that was cited by the Examiner. Applicants disagree that general knowledge and level of skill in the art cannot be used to show possession of the genus. The claims are not drawn to making a substrate; they imply that the substrate already has been made. Materials that cannot form substrates or those that cannot be used to make substrates with the directional and height uniformity elements of Applicants' claims are known to a person skilled in the materials art. In addition, such materials are excluded from the claims because the claims require that such a substrate exist.

With respect to the chemical moieties (Examiner's assertion numbered 5, *supra*), one must again consider the general knowledge and level of skill in the art. The chemical moieties must be those useful with array technology, such as biopolymers, for example polynucleotide sequences. One would infer from the operability element of the claims (*a method of fabricating an array of multiple features of different chemical moieties on a substrate surface*) that the chemicals actually form features. One skilled in the array art would know not to deposit chemicals that cannot be useful with array technology or those that cannot form features. Chemicals without these criteria are excluded from the claims as inoperative.

Two recent court decisions make it clear that a determination of what is needed to describe generic claims depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter. See *Capon v. Eshar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). The *Capon* court also considered that the "present scientific capability" of the routineer as a factor to consider. *Capon* at 1357.

Further, in *Bilstad v. Wakalopoulos*, 386 F.3d 1116 (Fed. Cir. 2004), the court remanded the case to the Board because the record contained no analysis of what skilled in the art would have understood from the disclosure or the degree of predictability of technical variations in this field of art. *Bilstad* at 1126.

For at least the reason that there is no analysis on this record applying the *Capon* factors, the rejection is improper. The Examiner has made only a passing

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reference to general knowledge and level of skill in the art, and then has dismissed such an analysis. As pointed out above, such an analysis would lead to the exclusion from the claims of many (if not all) of the embodiments that the Examiner maintains are not described.

Withdrawal of this rejection is respectfully requested.

Scope of Enablement

Claims 28, 29, 31, 35, and 37-45 were rejected under 35 U.S.C. § 112, first paragraph for being enabled for forming an array of oligonucleotides on a rectangular substrate of drawn glass, but allegedly not being enabled for methods that lead to the production of *any* chemical moiety on *any* substrate surface. This rejection is respectfully traversed.

The Examiner has repeated many of the same arguments regarding inoperable embodiments that were used in the written description requirement rejection. Applicants' reiterate their arguments above with respect to the rationale that should be used with respect to the exclusion of inoperative embodiments. The *Capon* factors for written description are not unlike the *Wands* factors for undue experimentation.

As pointed out above, the claims contain an operability element by virtue of reciting *a method of fabricating an array of multiple features of different chemical moieties on a substrate surface*. Therefore, inoperative embodiments that cannot be used to practice this method are not included within the scope of the claim. *Union Carbide Chemicals & Plastics Tech. Corp v. Shell Oil Co.*, 308 F.3d 1167 (CAFC 2002).

Furthermore, the Court has held that it is not a function of the claims to specifically exclude possible inoperative embodiments. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). A claim may contain operative embodiments and inoperative embodiments. There is no requirement that every embodiment be an operative embodiment. Only when the number of inoperative embodiments becomes significant, so as to require undue experimentation by the routineer to determine operative embodiments, does the issue of lack of enablement come into play. *Ibid*.

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Applicants submit (for the reasons presented above in the arguments against the written description rejection) that the specification evinces that the experimentation required for the exclusion of inoperative embodiments and for the determination of operative embodiments would be routine, and not undue. In addition, because the Examiner has not established that the claims contain such a significant number of inoperative embodiments that the experimentation for the exclusion of these embodiments and the determination of operative embodiments would be undue, the claims are enabled for the full scope thereof.

Withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 USC § 102

Claim 45 was rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cremer et al. *J Am Chem Soc* 1999, 121:8130-31 ("Cremer"). This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

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The Examiner asserted that:

Here, Cremer et al. measure and compare the height of the chemical features along the surface of the planar chip in all directions. For example the height of the square wells that contain lipids is ~ 5 nm higher than the wells that do not contain a lipid bilayer (e.g., see figure 4). In addition, the hydrophobic barriers between each square well was also measured and ranged between 25 μ m to 250 μ m in thickness (e.g., page 8131, column 2, "Up to now we have experimented with square well plates from 25 μ m \times 25 μ m to 250 μ m \times 250 μ m with

hydrophobic partitions ranging from 25 μ m to 250 μ m in thickness"). Thus, all heights in every direction along the planar surface were measured and compared, which would include a first and second direction. In addition, Cremer et al.

Office Action at pages 14-15.

However, the Examiner's remarks regarding the height of wells containing lipids indicate that height uniformity was measured **after** deposition of the lipids. However, Applicants' claim recites that height uniformities of the substrate are compared **before** placement of the chemical moieties upon the substrate.

In addition, the Examiner has interpreted the quoted passage of Cremer to mean that, for example, a single substrate may contain hydrophobic partitions of different thicknesses, ranging from 25 μ m to 250 μ m. However, the very next sentence after the quoted passage in Cremer states, "[a]ll sizes appeared to work equally well as the data presented here." Cremer at page 8131, second column (emphasis added). Therefore, one would reasonably interpret the disclosure of the 25 μ m to 250 μ m partition thickness range to mean that a plurality of substrates, each containing the **same size** partitions were intended, and that all worked equally well.

The Examiner's rejection appears to be based on inherency and on an interpretation of Cremer that amounts to a *possibility* that different sized partitions are present on a single substrate. The Examiner has not supported the rejection by factual and technical grounds establishing that the inherent feature must flow as a **necessary conclusion**, not simply a *possible* conclusion, from the teaching of the cited art. As such, there is no anticipation.

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Further, the Examiner appears to be asserting that Cremer chose between depositing three different dyes vertically, rather than at a slightly more skewed angle. However, there is nothing in Cremer that would indicate that anything but vertical deposition was contemplated. One again, the Examiner has not supported the rejection by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a *possible* conclusion, from the teaching of the cited art.

Accordingly, because each and every element as set forth in the claim is not identically described, either expressly or inherently, in Cremer, there is no anticipation.

Withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 USC § 103

Claims 28 and 45 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cremer, *supra*, in view of Lemmo et al. *Anal Chem* 1997, 69:543-51 and Baldeschwieler et al. (WO 95/25116). This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed method. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations (MPEP § 2143). The teaching or suggestion to arrive at the claimed method and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure (MPEP § 2143 citing with favor, *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

With respect to Claim 45, the Examiner's only rationale for obviousness is that because Cremer anticipates the claim, it renders the claim obvious as a result. Applicants presume that the Examiner perceives some difference(s) between Cremer and Applicants' Claim for there to be a basis for rejection under 35 U.S.C. § 103(a). However, the Examiner has not presented a proper analysis of obviousness under the standard enunciated by the Supreme Court in *Graham v. John Deere*, 383

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U.S. 1, 148 USPQ 459 (1966). Such an analysis includes a recitation of the perceived difference(s) between the claim and the cited art.

Applicants are at a loss with regard to responding to this rejection unless they know the proper basis for the rejection. Clarification is respectfully requested.

With respect to Claim 28, the Examiner recognized that Cremer does not disclose the use of a pulse-jet printer to deposit the chemical moieties. The secondary documents were cited by the Examiner in an effort to remedy the deficiency in Cremer. The secondary documents were cited only for their disclosure of using pulse-jet printers in the synthesis of combinatorial libraries.

Therefore, the secondary documents do not remedy the deficiency of Cremer because, as pointed out in the rejection under 35 U.S.C. § 102(b), they do nothing to provide the elements missing from Cremer vis-à-vis the rejected claims. The disclosure of pulse-jet printers does not and cannot supply the factual and technical grounds necessary to establish inherency. Accordingly, for at least the reason that the combination of cited documents does not teach or suggest all of the elements of Applicants' claims, there is no *prima facie* obviousness.

Withdrawal of this rejection is respectfully requested.

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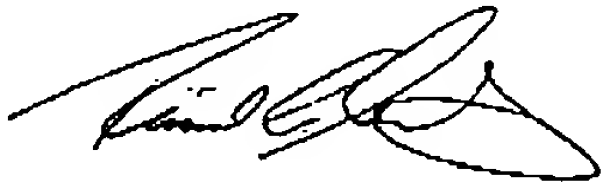
CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone John Brady at (408) 553-3584.

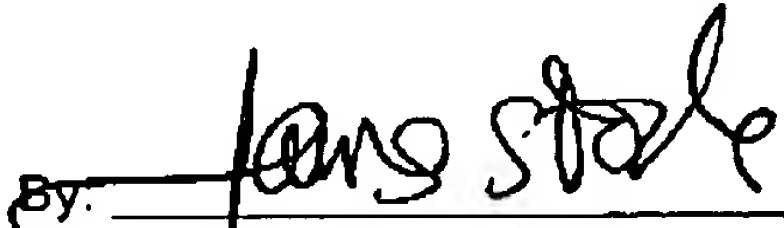
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10004190-1.

Respectfully submitted,

Date: 9/26/06


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